

## EXHIBIT 132



P H A R M A C E U T I C A L S

**Endo Pharmaceuticals  
Meeting with Drug  
Enforcement  
Administration**

September 30, 2003

Strictly Proprietary and Confidential



P H A R M A C E U T I C A L S

## Meeting Overview

Daniel Carbery, Group VP, Operations

George Stevenson, VP, Generic Business Unit

Jill Connell, Director, Supply Chain Management

Bob Barto, Director, Regulatory Affairs

Sue Tolen, Supply Chain Analyst

Strictly Proprietary and Confidential



## **EN3218 Marketing Plan**

George Stevenson  
VP, Generic Business Unit

Strictly Proprietary and Confidential

## **Oxycodone ER (EN3218) Background – Generics v. Brands**

- Brand products (NDA's) have to undergo clinical trials to receive FDA approval.
- Generic products (ANDA's) have to demonstrate they are biochemically equivalent – called bioequivalent by the FDA – to receive FDA approval.
- Once product deemed to be bioequivalent, it receives "AB" rating from FDA.
- Endo has received tentative approval from FDA for Oxycodone ER.
  - Bioequivalent to Oxycontin®
  - AB rated to Oxycontin®

Strictly Proprietary and Confidential



4

## Oxycodone ER (EN3218) Generic Marketplace Background

- Generics receiving AB rating from FDA can be substituted for the brand.
- Endo customers for generics are retailers and wholesalers and not physicians.
  - CVS, Walgreens, Wal-Mart, McKesson
  - Generics require 3 national account managers for entire US vs. 100's of sales reps to visit doctors for brand products.
- Because generics are equivalent yet cost less than brands, managed health care, insurance companies, HMO's and Medicaid force generic substitution.
  - 48 states require automatic substitution of AB rated generics for brand at the retail pharmacy.

Strictly Proprietary and Confidential



5

## Oxycodone ER (EN3218) Generic Conversion of Brands

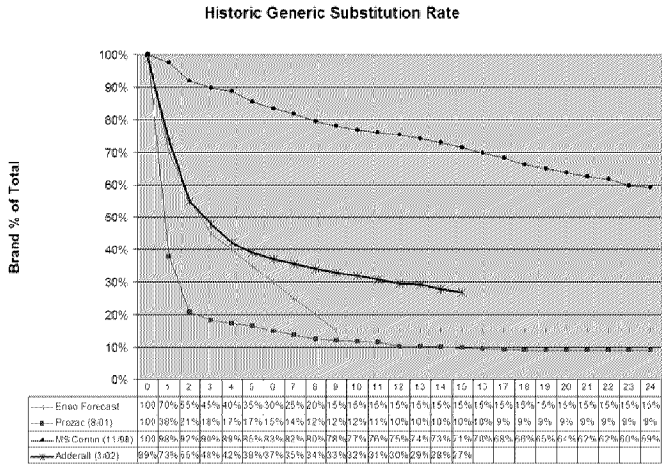
- Market drives conversion of brand to AB rated generic.
  - Forced by automatic substitution laws.
  - Forced by managed care, HMO's and insurance companies and Medicaid.
    - Lower co-pay for AB rated generic v. Brand
    - Public pressure to lower healthcare costs
- Information technology has led to greater market efficiency in ensuring mandatory substitution of AB rated generics for brands.
- Recent AB rated generic conversion of equivalent brand approaching 90% within 30 days.
  - Prozac® – commonly prescribed for depression converted 80% in 30 days to AB rated fluoxetine.
    - Eye opening because of speed of generic conversion of the brand.
    - Market efficiency overcame expected brand loyalty.
- Endo quota forecast conservative when viewed in light of Prozac® conversion to generic equivalent.

Strictly Proprietary and Confidential



6

# Recent Examples of Brand Conversion by AB rated Generic Equivalents



Strictly Proprietary and Confidential



7





## **Endo Risk Management Plan**

Bob Barto  
Director, Regulatory Affairs

Strictly Proprietary and Confidential

## **Risk Management Plan (RMP)**

- FDA view of RMP
  - Education
  - Surveillance
  - Labeling
- Endo's response to RMP

Strictly Proprietary and Confidential



5

## **Objectives of a Risk Management Plan (RMP)**

In general the FDA believes that a RMP should address 3 elements:

- Risk of accidental exposure - especially in Modified Release (MR) products with large amounts of opioid.
- Improper patient selection – how should a physician be selecting patients.
- Risk for abuse and misuse – how can we reduce risk for patient and community.

Strictly Proprietary and Confidential



## **Elements of a Risk Management Plan (RMP)**

Education – who should be educated, and nature of education.

■ Patient and caregiver – educate with regards to risk, use and protection from accidental ingestion via:

- Patient Package Insert (PPI)
- Package Insert

Strictly Proprietary and Confidential



11

## **Elements of a Risk Management Plan (RMP)**

From a risk management perspective, and according to the FDA, Endo's educational programs should address the following areas:

- Awareness of safe prescription practices
- Signs and symptoms of abuse
- Awareness of drug-seeking behavior for non-medical purposes
- Avoidance of unintended exposure in households

Strictly Proprietary and Confidential



12

## **Elements of a Risk Management Plan (RMP)**

Surveillance Plans - how does Endo plan to detect problems as they arise? Specifically the FDA is interested in:

- The details of our planned surveillance.
- Which databases does Endo plan on monitoring?
- How often would the databases be monitored?
- What are the plans for submitting reports to the FDA?

Strictly Proprietary and Confidential



13

## **Elements of a Risk Management Plan (RMP)**

- Intervention - if a problem is detected and Endo observes disproportionate rates of abuse or signals, what focused intervention will be employed? Focused education and/or law enforcement notification are two possible interventions.
- No specific list exists of what should be included in an intervention plan.

Strictly Proprietary and Confidential



14

## RMP – Product Labeling

- Product labeling – by FDA regulation, the product labeling **MUST** be identical to the reference listed drug (OxyContin®).
- Patient Package Insert - translates the Product Information into terms understandable by a typical patient (approximately a 6th grade level)

Strictly Proprietary and Confidential



15





PHARMACEUTICALS

## **Endo's response to RMP**

Current and Under Development

Strictly Proprietary and Confidential

## **RMP - Educational Activities**

- Endo has developed and continues to develop educational activities geared to pharmacists, physicians and patients on the use of opioids in general.
- These activities are part of an established, on-going effort to educate patients and the healthcare community regarding safe and effective opioid use.

Strictly Proprietary and Confidential



17

## RMP - Educational Activities

### **National Initiative on Pain Control (NIPC):**

- The "National Initiative on Pain Control" is a CME-accredited educational program established to advance physician education and help physicians improve outcomes for their patients with pain. The faculty consists of physicians, nurses and pharmacists with an established expertise in the diagnosis and treatment of chronic pain. The intended audience for the NIPC initiatives includes internists, family physicians, osteopathic medicine specialists, general neurologists and other clinicians who manage patients with chronic pain.
- The program currently covers two broad therapeutic areas: 1) assessment and treatment of neuropathic pain; 2) principles and prescribing considerations for the appropriate use of opioid analgesics.

Strictly Proprietary and Confidential



## RMP - Educational Activities

### **NIPC Participant Guide:**

- Provided to every participant in the live CME-accredited lectures and symposia. Purpose is to reiterate the CME learning objectives, to provide hard copies of the core curriculum slides, and to provide space for participants to record notes on the faculty presentations. Each participant guide also contains a copy of the CD-ROM resource kit which the clinician can utilize to improve patient management.

### **NIPC Audioconference Guide:**

- Provided to all registrants in the interactive audio conferences. The Audioconference Guide provides a means for the participants to view the core curriculum slides at their desks, while participating in the interactive audioconference. Each audioconference guide also contains a copy of the CD-ROM clinician resource kit.

### **NIPC Pain Management Today Newsletter:**

- The NIPC *Pain Management Today* newsletter is a 16-page CME-accredited publication distributed three times annually to 60,000 physicians who manage chronic pain patients. The publication is intended as a resource which provides timely articles of clinical importance, patient assessment/management resources, case studies, and a clinical Q&A forum on chronic pain.

Strictly Proprietary and Confidential



15

## RMP - Educational Activities

### **Painedu Website and Manual:**

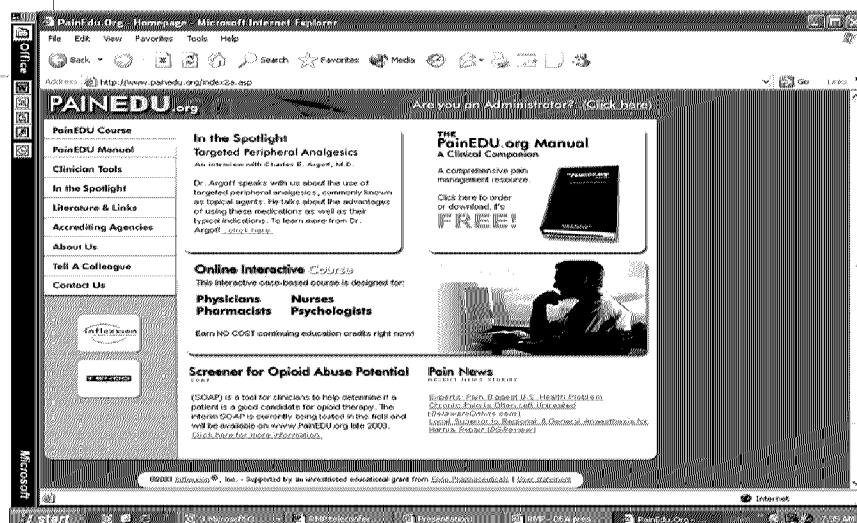
- [www.Painedu.org](http://www.Painedu.org) consists of a website and pocket manual created by Inflexxion, a multimedia-based technology company which specializes in the development and delivery of scientifically-based behavioral health interventions in the fields of oncology, pain medicine, and addiction medicine. Painedu utilizes nationally-recognized experts within the behavioral health, oncology, pain medicine and addiction medicine fields to develop the content for both the website and the pocket manual. The website is accredited for continuing medical, pharmacy, nursing and psychology education. The manual is available both electronically and in hard copy. Endo supports Painedu through an unrestricted educational grant.

Strictly Proprietary and Confidential



20

## RMP - Educational Activities



Strictly Proprietary and Confidential



21

## RMP - Educational Activities

### **Pain in Oncologic and AIDS Patients Handbook:**

- This handbook was authored by Russell Portenoy, MD, Chairman of the Department of Pain Medicine and Palliative Care, Beth Israel Medical Center, New York. The handbook provides clinically relevant information on the diagnosis and treatment of pain in oncologic and AIDS patients. Endo has purchased quantities of the handbook to distribute through their Scientific Affairs Department.

Strictly Proprietary and Confidential



22

## RMP - Educational Activities

### **Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain Handbook:**

- This handbook was prepared by a multidisciplinary committee of the American Pain Society to disseminate current information on effective therapy for acute pain and cancer pain to a broad audience of clinicians. Endo has purchased quantities of the handbook to distribute through their Scientific Affairs Department.

Strictly Proprietary and Confidential



23



## RMP - Educational Activities

### **AAPM/APS Consensus Statement on the Use of Opioids for the Treatment of Chronic Pain:**

- This joint consensus statement was prepared by the American Academy of Pain Medicine and the American Pain Society to provide guidance to clinicians on the undertreatment of pain; provide clarity on commonly-held assumptions regarding addiction, diversion, tolerance, and side effects; and to promulgate principles of good medical practice with regards to opioid analgesics. Endo has purchased quantities of the Consensus Statement to distribute through its Scientific Affairs Department.

Strictly Proprietary and Confidential



24

## RMP - Educational Activities

### **Practitioner's Guide to Prescribing Opioid Analgesics for Persistent Pain Handbook:**

- This handbook, authored by Perry Fine, MD and Russell Portenoy, MD, is expected to be published by McGraw Hill during the first quarter of 2004. The handbook is intended to provide the essential information necessary for physicians to responsibly prescribe opioid analgesics for persistent pain, including both clinical and risk management considerations. The handbook development is being supported through an unrestricted educational grant from Endo.

Strictly Proprietary and Confidential



25

## RMP - Educational Activities

### **Decision Support Tool to Assist in Opioid Drug Rotation (DST-O):**

- The Decision Support Tool to Assist in Opioid Drug Rotation (DST-O) is being developed by Inflexxion, a multimedia-based technology company which specializes in the development and delivery of scientifically-based behavioral health interventions in the fields of oncology, pain medicine, and addiction medicine. The purpose of the tool is to provide a **systematic, scientifically/clinically validated tool** to assist clinicians in making rational decisions regarding opioid rotation in patients who are experiencing either inadequate pain control or intolerable side effects. The objective is to enhance patient response and improve clinical outcomes; content for the tool will be provided by national experts in chronic pain management. Phase I of the DST-O development is currently underway is expected to be completed by end of 1Q 2004. Endo is supporting the development of the tool through an unrestricted educational grant.

Strictly Proprietary and Confidential



26

## RMP - Educational Activities

### **Patient Brochure on Opioid Analgesics:**

- This patient brochure, which is currently in draft form, is being developed by Russell Portenoy, MD, Chris Pasero, RN, and Margo McCaffery, RN. The brochure is intended to provide basic information on: opioid analgesics; their role in pain management; their potential side effects; the potential for addiction in patients taking opioids for the management of pain; and patient information on how to take their medication and track their pain. The brochure, when completed and approved, will be disseminated broadly through the Endo sales force, the Scientific Affairs Department and the Endo corporate website. The brochure will be available in both print and electronic versions.

Strictly Proprietary and Confidential



27

## RMP - Educational Activities

### **Screening for Opiate Addiction Potential Tool (SOAP)**

- Endo is currently supporting and will continue to support the development of what is referred to here as the SOAP tool – a prospective, self report screening tool funded by grants from NIDA and the National Institutes of Health (NIH), and developed by a team from Harvard University, Brigham and Women's Hospital and Inflexxion, a consulting company with expertise in development of screening tools.
- The SOAP tool will be developed by Inflexxion, a Newton, Massachusetts-based disease management and multimedia product development company with specific expertise in the fields of pain management and addiction medicine. Inflexxion will develop the screening tool under the auspices of a NIDA/NIH grant, with input and review by a scientific advisory group of national pain medicine and substance abuse experts.

Strictly Proprietary and Confidential



28

## RMP - Educational Activities

### The SOAP Screening Tool

- The SOAP tool will be a brief screening, self-report, tool for those chronic pain patients being considered for opioid therapy. It will be easily completed and scored in less than 10 minutes in the waiting room of a physician's office or alternatively could be completed prior to the visit either as a brief paper questionnaire, online, or through an Interactive Voice Recognition (IVR) system. Such a tool could help classify patients along a continuum of greater or lesser likelihood of encountering problems during a regimen of opioid medications. This information, along with interpretive cutoffs, would inform the healthcare provider that a given patient may require extra monitoring while on pain medications, or perhaps, additional or alternative treatments should be considered.

Strictly Proprietary and Confidential



25

## RMP - Educational Activities Under Development

- Endo will develop and implement educational programs for physicians, pharmacists, nurses, other allied healthcare professionals, patients and their families on the appropriate use of opioid analgesics. Although Endo funds these programs with an unrestricted educational grant, and thus relinquishes control of content to the CME developers, Endo will stress the requirement for discussion of risk management and would ask that the following elements be included in all programs:
  - Differentiation between physical dependence, tolerance, pseudoaddiction and addiction
  - Selection of patients for whom an extended release opioid is appropriate (type and duration of painful condition)
  - Initial assessment of patient including pain assessment tools prior to initiation of therapy with an extended release opioid
  - Reassessment of patient once therapy is initiated
  - Appropriate documentation for patients prescribed a long acting opioid
  - The importance of patient and family/caregiver education

Strictly Proprietary and Confidential



30

## **RMP - Educational Activities Under Development**

- Satellite symposia and educational programs done in conjunction with professional congresses such as
  - American Pain Society
  - American College of Physicians
  - Oncology Nursing Society
  - American Society of Clinical Oncology
  - Multi-National Association of Supportive Care in Cancer
  - Society for Teachers of Family Medicine
  - American Society of Healthcare System Pharmacists

Again, these satellite symposia are funded through an unrestricted educational grant given to the program organizers. Endo will make the organizers aware of the need for balance on the issues of risk management

Strictly Proprietary and Confidential



31



## **RMP - Educational Activities Under Development**

- Patient and family education pamphlets on the importance of compliance with opioid analgesic treatment regimens. The pamphlets will include any warnings and precautions from the Product Information with respect to appropriate dosing, potential side effects and their management, and the risks associated with extended release opioids when they are taken inappropriately or by someone other than the patient for whom they were prescribed.
- Pharmacy education materials which stress the importance of the relationship between the pharmacy and the prescribing physician in detection of abuse or diversion of extended release opioids. Endo will provide pharmacies with patient education tools similar to the materials provided to physicians that allow for discussion between the pharmacist and patient on the appropriate use of extended release opioid analgesics at the point of dispensing.
- A risk management "kit" for physicians with pain assessment tools, educational materials for both patients and physicians, a prototype patient /physician pain management contract, and tools for assessing the patient's risk for abusing their medication.

Strictly Proprietary and Confidential



32

## RMP Post-Marketing Safety Surveillance

### Post-marketing Adverse Event Surveillance

- The Clinical Drug Safety/Pharmacovigilance Department will conduct proactive surveillance of all adverse event reports received via post-marketing surveillance (spontaneous, scientific literature, post-marketing clinical investigations, and post-marketing epidemiological surveillance studies). Endo will review, investigate, process, and track adverse events for surveillance and safety signal detection.
- Reports of all serious adverse events to the FDA will be made in accordance with current Federal Regulations. In addition, Endo will send for a period of two (2) years, from the date of launch, adverse event reports of diversion, abuse, dependence, and overdose with the use of oxycodone extended release tablets in an expedited manner (15-day Alert), whether or not the experience is unexpected according to the approved labeling.

Strictly Proprietary and Confidential



33

## **RMP Post-Marketing Safety Surveillance**

### **Post Marketing Adverse Event Surveillance**

- **Periodic Reports** - Endo will assemble and submit periodic reports for all adverse events received for oxycodone extended release tablets in accordance with current Federal Regulations.

Strictly Proprietary and Confidential



34

## RMP Post-Marketing Safety Surveillance

### Endo Safety Review Board (ESRB)

- Endo has an established Safety Review Board (ESRB) to review adverse events and identify new safety signals and trends for Endo products. The ESRB will review aggregate adverse event data received for oxycodone extended release tablets on a quarterly basis at a minimum. However, if the Endo identifies a trend or signal prior to the quarterly review, the ESRB will address these issues promptly and independently.
- The ESRB is a multi-disciplinary team with representatives from Medical Affairs, Scientific Affairs, Clinical Operations, Regulatory Affairs, Project Management, Clinical Drug Safety/Pharmacovigilance, and Pre-Clinical Drug Safety. The ESRB will review adverse event data of oxycodone extended release tablets that have been collected as part of the post-marketing safety surveillance and ongoing clinical trial data. As part of this surveillance, ESRB will investigate and review all cases of clinical significance, drug abuse, drug dependence, and drug overdose to detect trends. Endo review will include patient demographics, physician demographics and information about the use of concomitant medications when available. In addition, information obtained will be compared to other products of potential abuse, in this therapeutic class. Once Endo has analyzed the information, if a trend is identified, additional education and safety measures will be initiated in the geographic area identified.

Strictly Proprietary and Confidential



35

## RMP Post-Marketing Safety Surveillance

### Secondary Databases

#### ■ Toxic Exposure Surveillance System (TESS)

- Toxic Exposure Surveillance System (TESS) data are compiled by the American Association of Poison Control Centers (AAPCC) in cooperation with the majority of US poison centers. These data are used to identify hazards early, focus prevention education, guide clinical research, and direct training. TESS data have prompted product re-formulations, repackaging, recalls, and bans; are used to support regulatory actions; and form the basis of postmarketing surveillance of newly released drugs and products. Endo will monitor oxycodone extended release tablets exposures in the AAPCC annual report, which is published every year. These exposures will be treated as adverse event reports and will be followed up with the individual Poison Control Center for submission to the FDA either on an expedited manner or in the periodic reports.

Strictly Proprietary and Confidential



36

## RMP Post-Marketing Safety Surveillance

### Secondary Databases

#### ■ Drug Abuse Warning Network (DAWN)

- The Drug Abuse Warning Network (DAWN) is an ongoing national survey of non-federal, short-stay general hospitals that have a 24-hour emergency department (ED). A representative sample of these hospital EDs submit data, and national estimates of ED drug episodes or drug mentions are generated for all such hospitals. The DAWN system also collects data on drug-related deaths from a non-random sample of medical examiners located in 41 metropolitan areas. The Substance Abuse and Mental Health Services Administration (SAMHSA) division of the Department of Health and Human Services (DHHS) supports DAWN. Endo will monitor the DAWN report, when it is released, to identify geographic trends, which may not be identified through standard post-marketing surveillance.

Strictly Proprietary and Confidential



37

## **RMP Post-Marketing Safety Surveillance**

### **■ Risk Intervention**

- If Endo identifies any geographical areas of abuse, dependence, misuse, or overdose with oxycodone extended release tablets, which may have been the result of diversion, these areas will be targeted for Risk Intervention. Intervention targeted to the identified areas will include education to consumers and health care providers (such as physicians, nurses, and pharmacists). In addition, Endo will work in conjunction with DEA to minimize diversion and misuse of oxycodone extended release tablets.

Strictly Proprietary and Confidential



38



## **Production Schedule**

Jill M. Connell  
Director, Supply Chain Management


Strictly Proprietary and Confidential



# Production Schedule

DEA Quota	Received initial quota 9/17 which supports 35 batches	Oct 15th; request for balance of 2003 quota	Receive approval of balance for 2003 quota by 11/3/03	Receive 2004 quota	
Oxycodone Procurement from Supplier	Shipped available Oxycodone 9/23	Remaining oxycodone to ship in October; pending Supplier's meeting quota approval	Ship oxycodone upon Supplier's availability		Ship available oxycodone
API release by Contract Manufacturer	Release of initial receipt of oxycodone	Release of remaining oxycodone	Release oxycodone		Release oxycodone
Production at Contract Manufacturer		Production of 35 of the 65 batches to support launch	Production of remaining launch requirements		Production of 2004 requirements
Released for Distribution				Launch Ready 1/1/04	
NOTE: This schedule assumes oxycodone supplier has oxycodone on hand at time of quota approval since normal lead time is 3 months					

Strictly Proprietary and Confidential

 4C

PHARMACEUTICALS